

## REMARKS

### I. Status of Claims

Claims 1-10 are pending in the subject U.S. patent application. Claims 1-6 have been rejected by the U.S. Patent and Trademark Office (hereinafter "the Patent Office"). Claims 7-10 currently stand withdrawn.

Claims 1 and 5 have been amended. New dependent claims 11 - 14 have been added. Support for the new claims and amendments can be found in the specification as originally filed. No new matter has been added.

Reconsideration of the application as amended and further in view of the remarks set forth herein below is respectfully requested.

### II. Response to Rejections under 35 U.S.C. § 102 over Streeter as evidenced by Hemmerich

Claims 1-6 have been rejected under 35 U.S.C. § 102(b) as allegedly being unpatentable over Streeter et al. (*J. Cell Biology*, 107, 1853-1862 (1988); hereinafter "Streeter") as evidenced by Hemmerich et al. (*Immunity*, 15, 237-247 (2001); hereinafter "Hemmerich"). The Patent Office contends that Streeter teaches a method of staining tissue from the small intestine and colon with MECA-79 antibody. The Patent Office contends that the binding of MECA-79 antibody to its antigen present in cells expressing a HEC-GlcNAc6ST gene encoding GlcNAc-6-sulfotransferase would be an inherent feature of the antibody and of any method in which the antibody was used. The Patent Office contends that Hemmerich supports this inherency by disclosing staining of tissue samples expressing HEC-GlcNAc6ST by the MECA-79 antibody.

After careful consideration of the rejection and the Patent Office's comments, applicants respectfully traverse the rejection and offer the following remarks.

Claims 1 and 5 have been amended to more particularly point out the claimed subject matter. Support for the amendments can be found throughout the application and specifically in at least Paragraphs [0019-0020], [0027], [0036], [0044], [0049],



[0051] and the Abstract of the published application. Dependent claims 11 -14 have been added. Support for these amendments can be found in the claims as originally filed and in at least Paragraphs [0028] and [0051] of the published application. No new matter has been added.

Independent claim 1 is directed to a method of examining colorectal cancer and colorectal adenoma by assaying for the binding of an antibody to an antigen (i.e., GlcNAc-6-sulfated sugar residues) present in cancer or adenoma cells (i.e., cells expressing HEC-GlcNAc6ST gene) but not present in normal cells (i.e., cells expressing GlcNAc6ST-1 or I-GlcNAc6ST gene). Independent claim 5 is directed to a method of examining colorectal cancer and colorectal adenoma by assaying for the binding of MECA-79 antibody or another antibody with the same binding specificity to tissues, body fluid, feces, or extract thereof. These claims have been amended to more particularly point out that the assays described are performed on patients in need of screening for colorectal cancer or adenoma; therefore the methods begin with the step, "providing a patient in need of screening for colorectal cancer or adenoma."

Applicants respectfully submit that neither Streeter nor Hemmerich describe a method of examining colorectal cancer or colorectal adenoma by detecting an antigen that is present in cells expressing a HEC-GlcNAc6ST gene and absent in cells expressing GlcNAc6St-1 or I-GlcNAc6ST genes. Nor do Streeter and Hemmerich describe any method of examining colorectal cancer or colorectal adenoma, including in patients in need of such screening. The cited references discuss experiments involving MECA-79 that were conducted only in mice. The MECA-79 staining disclosed therein was not performed on feces, body fluids, or extracts thereof. The references do not mention cancer, adenoma, or providing a patient in need of screening for either; nor do they inherently perform Applicants' methods. Therefore, Applicants respectfully submit that a *prima facie* case of anticipation under 35 U.S.C. 102(b) has not been established. Furthermore, Applicants submit that even if the cited references are combined, there is no teaching or suggestion in Streeter and Hemmerich of Applicants' invention.



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Accordingly, applicants respectfully request the withdrawal of the rejection of claims 1-6 under 35 U.S.C. § 102(b) over Streeter as evidenced by Hemmerich and further ask that claims 1-6 and 11-14 be allowed at this time.

#### CONCLUSIONS

Should there be any minor issues outstanding in this matter the Examiner is respectfully requested to telephone the undersigned attorney. Applicants respectfully submit that claims 1-6 and 11-14 are clearly allowable for the reasons stated herein. Early passage of the subject application to issue is earnestly solicited.

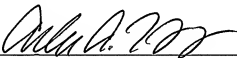
#### DEPOSIT ACCOUNT

The Commissioner is hereby authorized to charge any fees associated with the filing of this correspondence to Deposit Account Number 50-0426.

Respectfully submitted,

JENKINS, WILSON, TAYLOR & HUNT, P.A.

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